K060896

JUN - 9 2006

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1) Submitter name, address, contact

Varian, Inc.
25200 Commercentre Drive
Lake Forest, CA 92630
(949) 770-9381

Contact: Lorna Gamboa

Date Prepared: March 24, 2006

2) Device Name

Proprietary Name: OnTrak TesTcup® II and OnSite CupKit™

Panel: Toxicology

Classification Name:	Product Code	Regulation Number
Enzyme Immunoassay, Amphetamines	DKZ	862.3100
Enzyme Immunoassay, Benzodiazepines	JXM	862.3170
Enzyme Immunoassay, Cocaine and Cocaine Metabolite	DIO	862.3250
Enzyme Immunoassay, Opiate	DJG	862.3650
Enzyme Immunoassay, Phencyclidine	LCM	Unclassified
Enzyme Immunoassay, Cannabinoids	LDJ	862.3870
Thin Layer Chromatography, Methamphetamine	DJC	862.3610

3) Predicate Device

We claim substantial equivalence to these legally marketed devices:

OnTrak TesTcup® II and OnSite CupKit™ , K033902, 01/20/2004

4) Device Description

The OnTrak TesTcup II and OnSite Cupkit assays contained in this submission are in vitro diagnostic tests intended for professional use in the qualitative detection of amphetamines (d,l-amphetamine 1000 ng/mL), benzodiazepines (oxazepam 200 ng/mL), cocaine metabolite (benzoylecgonine 300 ng/mL), methamphetamine (d-methamphetamine 500 ng/mL), and methamphetamine (d-methamphetamine 300 ng/mL), morphine (morphine 300 ng/mL), and morphine (morphine 2000 ng/mL), PCP (phencyclidine 25 ng/mL) and THC (11-nor-Δ^9-THC-9-carboxylic

acid 50 ng/mL).

The assays are based on the principle of microparticle capture inhibition. The test relies on the competition between drug, which may be present in the urine being tested, and drug conjugate immobilized on a membrane in the test chamber.

Urine is collected directly in the test cup provided. The drug profile card is placed in the samples by inserting it into the lid holder, then securing the lid onto the cup. Urine is drawn in the profile card by capillary action and reacts with antibody-coated microparticles and drug conjugate present on the membrance. In the absence of drug, the antibody is free to interact with the drug conjugate, causing the formation of a blue band.

When drug is present in the specimen, it binds to the antibody-coated microparticles. If sufficient drug is present, the microparticles are inhibited from binding the drug conjugate and no blue band is formed at the result window. A preliminary positive ("non-negative") result is the absence of a blue band.

An additional antibody/antigen reaction occurs at the "VALID" area. The "VALID" blue band forms when antibodies, which are imbedded in the reagent membrane, interact with and bind to the antigen on the blue microparticles.

5) Technological Characteristics

All drug test strips contained in the modified TesTcup II and CupKit products have been previously reviewed by FDA under the 510(k) numbers indicated in Section 3 of this summary.

Like the predicate devices, the modified TesTcup II and CupKit utilize microparticle capture inhibition.

6) Substantial Equivalence

The modified TesTcup II and CupKit devices have the same intended use and incorporate the same fundamental scientific technology as the predicate devices.

	TesTcup II and CupKit	**Predicates**
Intended Use	Qualitative detection of drugs in urine	Same
Scientific Technology	Microparticle capture inhibition	Same
Sample Matrix	Urine	Urine

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Lorna Gamboa
Regulatory Affairs Manager
Varian, Inc.
Consumable Products
25200 Commercentre Drive
Lake Forest, CA 92630

JUN - 9 2006

Re: k060896
Trade/Device Name: OnTrak TesTcup® II and OnSite CupKit™
Regulation Number: 21 CFR§862.3610
Regulation Name: Methamphetamine test system
Regulatory Class: Class II
Product Code: DJC, DKZ, JXM, DIO, DNK, LCM, LDJ
Dated: March 24, 2006
Received: April 3, 2006

Dear Ms. Gamboa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

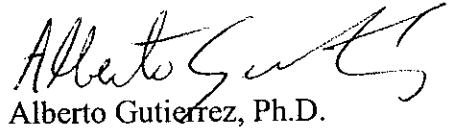
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060896

Device Name: OnTrak TesTcup® II and OnSite CupKit™

Indications For Use:

TesTcup II and CupKit products are in vitro diagnostics tests intended for professional use for the qualitative detection of drug or drug metabolite in urine at or above the stated cutoff concentrations:

Cutoff Concentrations:

Amphetamines:	1000 ng/mL	Morphine:	300 ng/mL
Benzodiazepines:	200 ng/mL	Morphine (M2K):	2000 ng/mL
Cocaine metabolite:	300 ng/mL	Phencyclidine (PCP):	25 ng/mL
Methamphetamine:	500 ng/mL	Tetrahydrocannabinols:	50 ng/mL
Methamphetamine:	300 ng/mL		

TesTcup II and CupKit products provide only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K060896